

We claim:

- 1) A pharmaceutical composition in form of a soft gel capsule resistant to gastric juice and soluble in intestine useful for the treatment of duodenal ulcers and related ailments which comprises of a gelatin shell resistant to gastric juice and soluble in intestine having an enteric polymer mixed into gelatin in the form of free acid or its salt and the capsule incorporating a composition comprising enantiomers of omeprazole such as esomeprazole, rabeprazole or its salts or its derivatives or their mixtures, a hydrophobic oily substance or a mixture of such oily substances, an alkaline inert reacting material, a suspending agent, a surface active agent and / or a solublising agent; wherein the resulting capsules being insoluble in aqueous medium up to a pH of 5.5 but quickly dissolving above pH of 6.0.
- 2) A pharmaceutical composition as claimed in claim 1 wherein the amount of enetiomers of omeprazole or its salts or derivatives or their mixtures present in the formulation is equivalent to one unit dose.
- 3) A pharmaceutical composition as claimed in claims 1 & 2 wherein the enteric polymer employed for coating the gelatin shell is selected from polymers such as hydroxypropyl methyl cellulose phthalate, alkyl methacrylate and methacrylic acid copolymers, polyvinyl acetate phthalate and the like.
- 4) A pharmaceutical composition as claimed in claim 3 wherein the enteric polymer employed is in the form of free acid or their ammonia or alkali metal salts.
- 5) A pharmaceutical composition as claimed in claims 3 & 4 wherein the amount employed ranging from 2.0 to 40.0 percent, preferably 5.0 to 25.0 percent by weight, with reference to the dried shell.
- 6) A pharmaceutical composition as claimed in claims 1 to 5 wherein the enantiomers of omeprazole or its salts or derivatives or their mixtures employed in the formulation is suspended / solubilised in a hydrophobic oily substance selected from

fats and oils of vegetable origin such as sesame oil, corn oil, maize oil, soybean oil, sunflower oil, arachis oil, gingly oil and the like; animal origin such as fish oil, pig oil, beef oil and the like; esters of straight chain aliphatic oils such as Sunsoft 700 P-2 (Taiho chemical company) Panasete 810 (Nippon oils and Fats); hydrogenated vegetable oils or a mixture thereof.

7) A pharmaceutical composition as claimed in claim 6 wherein the amount of hydrophobic oily substance used ranging from 25.0 to 95.0 percent, preferably 35.0 to 90 percent by weight with reference to the contents filled in capsules.

8) A pharmaceutical composition as claimed in claims 1 to 7 wherein substances such as colloidal silicon dioxide, polyvinylpyrrolidone, microcrystalline cellulose are used as dispersing agents in an amount ranging from 0.5 to 20.0 percent preferably 1.0 to 10.0 percent by weight and materials such as lecithin, polyoxyethylene castor oil derivative such as Cremophor RH 40 (polyoxyl 40 hydrogenated castor oil), Cremophor EL (polyoxyl 35 castor oil, BASF) polyoxyethylene sorbitan fatty acid esters, Gelucire 33/01(glycerol esters of fatty acids), sodium lauryl sulphate, docusate sodium and the like are used as surface active agent and / or a solublising agent.

9) A pharmaceutical composition as claimed in claim 8 wherein the amount of surface active agent and/or solublising agent ranging from 2.0 to 20.0 percent, preferably 4.0 to 15.0 percent by weight, with reference to the contents filled in capsule.

10) A pharmaceutical composition as claimed in claims 1 to 9 wherein materials such as the sodium, potassium, calcium, magnesium and aluminium salts of phosphoric acid, carbonic acid, citric acid, other suitable organic or inorganic acids; meglumine, triethanolamine and the like are used as alkaline inert reacting materials.

11) A pharmaceutical composition as claimed in claims 1 to 10 wherein the amount ranging from 5.0 to 40.0 percent, preferably 10.0 to 25.0 percent by weight, with

reference to the contents filled in capsule.

- 12) A pharmaceutical composition as claimed in claims 1 to 11 wherein the soft gel capsules are treated with a gelatin cross linking agent such as formaldehyde, glutaraldehyde, crotonaldehyde, 1,2-phthalic acid aldehyde, 1,3-phthalic acid aldehyde, 1,4-phthalic acid aldehyde; carboimides such as 1-ethyl-3-[2-morpholinyl-(4)-ethyl]-carboimide-metho-P-toluene-sulfonate and the like.
- 13) A pharmaceutical composition as claimed in claims 1 to 12 wherein the soft gel capsules are treated with cold dilute solutions of acids selected from hydrochloric acid, sulphuric acid, nitric acid, phosphoric acid, citric acid, propionic acid, benzoic acid, oxalic acid, maleic acid, fumaric acid and the like.
- 14) A process for the preparation of a pharmaceutical composition in the form of a soft gel capsule resistant to gastric juice and soluble in intestine useful for the treatment of duodenal ulcers and related ailments which comprises forming a gelatin shell which is resistant to gastric juice and soluble in intestine having an enteric polymer in the form of free acid or its salt, and incorporating into the resultant capsule a composition comprising esomeprazole or rabeprazole or other enantiomers of omeprazole or its salts or derivatives or their mixtures, a hydrophobic oily substance or a mixture of such substances, an alkaline inert reacting material, a suspending agent, a surface active agent and / or a solublising agent; wherein the resultant capsules being insoluble in aqueous medium up to a pH of 5.5 but quickly dissolve above pH of 6.0.
- 15) A process as claimed in claim 14 wherein the amount of esomeprazole or rabeprazole or other enantiomers of omeprazole or its salts or derivatives or their mixtures present in the formulation is equivalent to one unit dose.
- 16) A process as claimed in claims 14 & 15 wherein the enteric polymer employed for coating the gelatin shell is selected from polymers such as hydroxypropyl methyl

cellulose phthalate, alkyl methacrylate and methacrylic acid copolymers, polyvinyl acetate phthalate and the like.

17) A pharmaceutical composition as claimed in claim 16 wherein the enteric polymer employed is in the form of free acid or their ammonia or alkali metal salts.

18) A process 16 & 17 wherein the amount employed ranging from 2.0 to 40.0 percent, preferably 5.0 to 25.0 percent by weight, with reference to the dried shell.

19) A pharmaceutical composition as claimed in claims 14 to 18 wherein the enantiomers of omeprazole or its salts or derivatives or their mixtures employed in the formulation is suspended / solubilised in a hydrophobic oily substance selected from fats and oils of vegetable origin such as sesame oil, corn oil, maize oil, soybean oil, sunflower oil, arachis oil, gingly oil and the like; animal origin such as fish oil, pig oil, beef oil and the like; esters of straight chain aliphatic oils such as Sunsoft 700 P-2 (Taiho chemical company) Panasete 810 (Nippon oils and Fats); hydrogenated vegetable oils or a mixture thereof.

20) A process as claimed in claim 19 wherein the amount of hydrophobic oily substance used ranging from 25.0 to 95.0 percent, preferably 35.0 to 90.0 percent by weight, with reference to the contents filled in capsules.

21) A process as claimed in claims 14 to 20 wherein substances such as colloidal silicon dioxide, polyvinylpyrrolidone, microcrystalline cellulose are used as dispersing agents in an amount ranging from 0.5 to 20.0 percent preferably 1.0 to 10.0 percent by weight and materials such as lecithin, polyoxyethylene castor oil derivative such as Cremophor RH 40 (polyoxyl 40 hydrogenated castor oil), Cremophor EL (polyoxyl 35 castor oil, BASF), Gelucire 33/01 (glycerol esters of fatty acids), polyoxyethylene sorbitan fatty acid esters, sodium lauryl sulphate, docusate sodium and the like are used as surface active agent and / or a solublising agent.

22) A process as claimed in claim 21 wherein the amount of surface active agent and/or solublising agent ranging from 2.0 to 20.0 percent, preferably 4.0 to 15.0 percent by weight, with reference to the contents filled in capsule.

5 23) A pharmaceutical composition as claimed in claims 14 to 22 wherein materials such as the sodium, potassium, calcium, magnesium and aluminium salts of phosphoric acid, carbonic acid, citric acid, other suitable organic or inorganic acids; meglumine, triethanolamine and the like are used as alkaline inert reacting materials.

10 24) A process as claimed in claims 14 to 23 wherein the amount ranging from 5.0 to 40.0 percent, preferably 10.0 to 25.0 percent by weight, with reference to the contents filled in capsule.

15 25) A process as claimed in claims 14 to 24 wherein the soft gel capsules are treated with a gelatin cross linking agent such as formaldehyde, glutaraldehyde, crotonaldehyde, 1,2-phthalic acid aldehyde, 1,3-phthalic acid aldehyde, 1,4-phthalic acid aldehyde; carboimides such as 1-ethyl-3-[2-morpholinyl-(4)-ethyl]-carboimide-metho-P-toluene-sulfonate and the like.

20 26) A process as claimed in claims 14 to 25 wherein the soft gel capsules are treated with cold dilute solutions of acids selected from hydrochloric acid, sulphuric acid, nitric acid, phosphoric acid, citric acid, propionic acid, benzoic acid, oxalic acid, maleic acid, fumaric acid and the like.

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